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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,362	10/30/2003	Edward W. Merrill	37697-0081	6751
26633	7590	07/23/2004	EXAMINER	
HELLER EHRMAN WHITE & MCAULIFFE LLP 1666 K STREET,NW SUITE 300 WASHINGTON, DC 20006			BERMAN, SUSAN W	
			ART UNIT	PAPER NUMBER
			1711	

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/696,362	Applicant(s) MERRILL ET AL.	
	Examiner Susan W Berman	Art Unit 1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 124-127 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 124-127 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/04</u> . | 6) <input type="checkbox"/> Other: ____. |

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Response to Request for Interference

Claims 124-127 of this application have been copied by the applicant from U. S. Patent No. 6,316,158. These claims are not patentable to the applicant because the instant specification is not found to be enabling for the claims presented. See the rejection under 35 USC 112 set forth below.

An interference cannot be initiated since a prerequisite for interference under 37 CFR 1.606 is that the claim be patentable to the applicant subject to a judgment in the interference.

Specification

The disclosure is objected to because of the following informalities: The amendment to the Specification on page 1 setting forth continuing data contains an error in the filing date of S.N. 08/726,313, said to be filed October 2, 1966.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 124-127 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process comprising providing an **ultrahigh molecular weight polyethylene** preform, heating the preform, after irradiation at a dose of 0.5 to 1,000 Mrads or to 100 Mrads or to 30 Mrads or to 20 Mrads or to 15 Mrads, to a temperature greater than the melting temperature or within the temperature ranges set forth on page 20 so that there are no detectable free radicals in the UHMWPE, and for the times set forth on pages 20-21, does not reasonably provide enablement for providing a “polyethylene” preform, for heating the preform to a “temperature greater than its melting temperature

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and less than its decomposition temperature for a time sufficient to increase its percent elongation to break properties”, for heating at temperature “from about 280⁰C to about 355⁰C”, or for subsequently irradiating with gamma radiation at a dose of about 0.5 to “about 10 Mrad” . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. See pages 11-12, 19, 20 and 21.

Specifically:

With respect to claim 124, the Examiner has not found any mention in the specification of the disclosed process being employed with polyethylene other than ultrahigh molecular weight polyethylene.

With respect to claims 124 or 127, the instant specification as originally filed does not provide basis for the phrase “and less than its decomposition temperature for a time sufficient to increase its percent elongation to break properties”. With respect to the phrase “temperature...less than its decomposition temperature for a time sufficient to increase its percent elongation to break properties” , the instant specification discloses heating in a temperature range of 137 ⁰C to 300 ⁰C. This range is inclusive of the 280 ⁰C and above temperature range disclosed in the ‘158 Patent. US ‘158 teaches that the “temperature range less than its decomposition temperature for a time sufficient to increase its percent elongation to break properties” is 280 ⁰C and above or from about 280 ⁰C to about 355 ⁰C. It is agreed that there is overlap in the temperature range from 280 ⁰C to 300 ⁰C, however, this overlapping range does not provide enablement for the instant claim recitation of 280 ⁰C to 355 ⁰C lacking any recognition in the instant disclosure as filed of the criticality of this temperature range and time for increasing percent elongation to break properties. The examiner has not found any mention of percent elongation at break. Strain at break and tensile elastic modulus are discussed in the specification as originally filed.

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With respect to claim 125, the instant specification as originally filed does not provide antecedent basis for the phrase “heating step is performed at temperatures from about 280°C to about 355°C”.

Applicant discloses heating from temperatures of about 137 °C to about 300 °C.

With respect to claim 126, the instant specification as originally filed does not provide antecedent basis for the phrase “wherein the perform is irradiated with gamma radiation at a dose of about 0.5 to “about 10 Mrad”. Applicant discloses irradiation with gamma radiation at a dose of from 0.5 to 1000 Mrads, 1-100 Mrads or preferably 4-30 Mrads, thus providing basis for a recitation of from 0.5 to 30 Mrads being closest to the range set forth in the claims of US ‘158. With respect to the phrase “irradiated with gamma radiation at a dose of about 0.5 to about 10 Mrad”, applicant’s disclosure provides enablement for a recitation of from 0.5 Mrad to 30 Mrads, 0.5 to 100 Mrads or 0.5 to 1,000 Mrads, but not from 0.5 to 10 Mrads. It is agreed that there is overlap with the range of 0.5 to 10 Mrads, however, this does not provide enablement for a claim recitation of 10 Mrads lacking any recognition in the disclosure as filed of the criticality of this upper limit of 10 Mrad radiation.

It is suggested that applicant present claims reciting heating to a temperature greater than its melting point within a temperature range of 137 °C to 300 °C and gamma radiation at a dose of from 0.5 Mrad to 30 Mrads to provide a tensile elastic modulus less than about 940 MPa. Applicant can then argue that the claims, if found patentable to applicant, recite subject matter that interferes with the subject matter claimed in US ‘158. See MPEP section 2307. If a claim in the instant application is not identical to a proposed count, applicant should explain why the claim corresponds to the proposed count.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 124-127 are rejected under 35 U.S.C. 102(b) as being anticipated by Saum et al (6,316,158). The instant claims are claims 1-3 and 25 copied from US '158 to Saum et al. The claims are rejected over Saum et al because the claims, as written, are not patentable to applicant because the claims, as written, are not enabled by the instant specification or the prior applications relied upon for an effective filing date as early as 02-13-1996, 10-02-1996 or 02-11-1997. See the rejection under 35 USC 112 set forth above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 124-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-130 of copending parent Application No. 10/197209. Although the conflicting claims are not identical, they are not patentably distinct from each other because the processes set forth in the corresponding claims overlap wherein the heating is at a temperature above the melting point and below the decomposition temperature for a time period from about 5 minutes to about 3 hours. The processes set forth in the dependent claims also overlap with

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respect to temperature, radiation dose and intended properties. Thus species within the instant claims are obvious from the limitations set forth in the claims of S.N. 197209.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-130 of copending parent Application No. 09/764,445. Although the conflicting claims are not identical, they are not patentably distinct from each other because the processes set forth in the corresponding claims overlap wherein the heating is at a temperature above the melting point and below the decomposition temperature for a time period from about 5 minutes to about 3 hours. The processes set forth in the dependent claims also overlap with respect to temperature, radiation dose and intended properties. Thus species within the instant claims are obvious from the limitations set forth in the claims of S.N. 197209.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan W Berman whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Susan W Berman
Primary Examiner
Art Unit 1711

SB
7/20/04